

**REMARKS**

In the Office Action of February 19, 2010, the Examiner has taken the words of applicant's claims and simply asserted, without basis, that the recited limitations are found in the cited references. Neither the references, nor anything one skilled in the art could deduce from them without using the teachings of applicant, support the Examiner's assertions.

I. Claims 4-6, 9-11, and 14 have been rejected under 35 U.S.C. 103(a) as being unpatentable over Sarin et al. (US 20040254586) in view of DiGioia et al. (US 6205411) Chen et al. (WO 02/062248). See ¶2 of the Office Action. These references and their actual teachings are now discussed in detail to show their inapplicability.

**Sarin et al., US 2000/02544586.**

It is asserted that Sarin teaches "a method executed in a computer system having at least one processor for determining axial rotation of a pelvis, comprising receiving information defining a coordinate system of said pelvis in the near AP direction; defining first and second landmarks of said pelvis, said landmarks separated from each other in at least an anterior-posterior direction; determining the transaxial displacement of said landmarks on said image; and using said displacement to determine the axial and transaxial rotations of said pelvis with respect to the plane of said image [0041] [0042] [0051] [0052]." (Office Action, ¶2). Sarin does no such thing.

What Sarin in fact does is concisely summarized at ¶ 0010 and 001 of his application:

[0010] The invention includes a method of determining the plane of a surgical patient's pelvis and inputting that plane into a computer via a tracking system, suitable for use in navigating partial or total hip replacement surgery, comprising the steps of: *aligning the patient in relation to a patient positioning frame with pelvic anatomical features of the patient disposed in secure mechanical relationship with corresponding patient-engaging features on the positioning frame; acquiring with a tracking system the positions of a plurality of index points, the index*

points constrained to lie in a predetermined relationship with an anterior pelvic plane (APP) defined by the patient-engaging features; and defining a pelvic plane by calculation based upon the acquired positions of the index points and the predetermined relationship between the APP and the index points.

[0011] The apparatus of the invention includes a patient positioning frame, adapted to adjustably mount in opposition to an adjustable backrest, and suitable for use in connection with computer assisted surgery for finding the orientation of a patient's pelvic plane. The frame comprises: at least one anterior superior iliac spine (ASIS) locating feature, adapted to engage in close relation to the patient's ASIS; and at least one pubic locating feature, adapted to engage in close relation to the patient's pubic symphysis, the ASIS and pubic locating features defining an anterior pelvic plane (APP). The pelvic locating frame further comprises a group of index features, the group constrained to maintain a predetermined rotational relationship to the anterior pelvic plane (APP) defined by the ASIS and pubic locating features.

(emphasis added).

The *patient positioning frame* is shown in Figure 2. It comprises a back rest assembly 200 and a support assembly 212:

[0028] FIG. 2 shows one embodiment of the invention. To hold the patient in the lateral decubitus position, the invention includes a back rest assembly 200.....

[0030] A pelvic locator assembly 212 is also shown in opposition to the back rest assembly 200, such that a patient can be disposed in between assemblies 200 and 212 and will be firmly clamped and secured.....

As seen from the above, the patient is literally clamped between the back rest assembly and the pelvic locator assembly.

The support assembly 212 carries pads (223a and 223b) to engage the left and right anterior superior iliac spines (ASIS), and a pubis locator 230:

[0030] .....At the end of the each horizontal member 220 and 222, there is an ASIS pad (223a and 223b) intended to press against and secure the patient by superficially engaging (two) ASIS.....Pubis locator 230 is

provided to firmly engage the pubic symphysis but is preferably padded to prevent undue discomfort.

The assembly 212 also carries a “touch plate” 250 on which are located “touch points” 252a, 252b, and 252c. These are used to define a coordinate reference system:

[0042] The positions of the three touch points define the orientation of a coordinate system fixed in relation to the touch plate of FIG. 4. The local coordinate system of the touch-plate in turn defines the anterior pelvic plane (APP) because the ASIS finders and the pubis finder are located in a fixed known position relative to the local coordinate axes of the touch plate.....

The locations of the touch points in three-dimensional space are determined by means of a surgical tracking system:

[0037] FIG. 4 shows the touch plate more closely. The three touch points 252a-252c (“index features”) are defined by features in elevated posts 280. Preferably, the index features are formed or machined to engage a known pointer of a trackable probe, for example as shown in FIG. 3 of U.S. Pat. No. 6,711,431.....

Thus, Sarin determines the anterior pelvic plane (APP) by mechanically clamping the patient in a frame; contacting standard reference points (the anterior superior iliac spines and the pubic symphysis) with pads affixed to the frame; and obtaining the coordinates of the pads (and thus the reference points) with known surgical navigation techniques. Sarin does *not* form an image of the pelvis and does *not* determine axial rotation of the pelvis with respect to the plane of the image. Indeed, Sarin teaches that image-forming methods are to be *avoided*:

[0008] More recently, U.S. Pat. No. 6,711,431 to Sarin et al. (Mar. 23, 2004, assigned to Kinamed, Inc.) describes methods, apparatus and tools for **image free**, computer assisted navigation of hip surgery. The methods discussed in that application involve acquisition and tracking of a patient's pelvic plane by locating certain anatomical landmarks. The disclosed methods are less complex and expensive than reliance on radiological **imagery**. In connection with the methods disclosed by Sarin, it would be

desirable to further facilitate reliable acquisition of the patient's pelvic plane.

(emphasis). This paragraph contains the only references to images in the entire application and it is wholly negative as to their use.

Summarizing, Sarin neither teaches nor suggests *any* of the following limitations expressly set forth in claim 4:

- *A method....for determining axial rotation of a pelvis from a single fluoroscopic image,*
- *receiving a fluoroscopic image of said pelvis in the near AP direction;*
- *defining first and second landmarks of said pelvis on said image;*
- *determining the transaxial displacement of said landmarks on said image;*
- *using said displacement to determine the axial rotation of said pelvis with respect to the plane of said fluoroscopic image.*

Similarly, Sarin neither teaches nor suggests *any* of the following limitations expressly set forth in claim 9:

- *A method....for determining the transaxial rotation of a pelvis from a single fluoroscopic image,*
- *receiving a fluoroscopic image of said pelvis in the near AP direction;*
- *defining first and second landmarks of said pelvis on said image;*
- *determining the axial displacement of said landmarks on said image;*
- *using said displacement as a measure of the transaxial rotation of said pelvis with respect to the plane of said fluoroscopic image.*

Thus, by itself, Sarin teaches *none* of the claimed elements of applicant's invention. Further, lacking a teaching of any of these elements, there is no basis for combining Sarin with any other reference –it can bring nothing to the combination.

#### **DiGioia et al., US 6,205,411**

The Examiner has asserted that DiGioia teaches

"superimposing landmark registration onto a fluoroscopic image, wherein rotation is taken as a function of displacement of the fluoroscopic images of a sample taken at known orientations to the image plane in order to aid in surgical simulations in preoperative planning minimizing the extent to which the pelvis must be exposed during the procedure (abstract) (column 11, lines 11-25) (Figure 2)." (Office Action, ¶2.)

DiGioia teaches no such thing.

Di Gioia teaches an apparatus for facilitating artificial implants:

The present invention is directed to an apparatus for facilitating the implantation of an artificial component in one of a hip joint, a knee joint, a hand and wrist joint, an elbow joint, a shoulder joint, and a foot and ankle joint. The apparatus includes a pre-operative geometric planner and a pre-operative kinematic biomechanical simulator in communication with the pre-operative geometric planner. (DiGioia, col. 4, l. 59-65).

The apparatus comprises a data source, a tracking device, and software to plan and track the implantation:

The apparatus 10 includes a geometric pre-operative planner 12 that is used to create geometric models of the joint and the components to be implanted based on geometric data received from a skeletal structure data source 13. The pre-operative planner 12 is interfaced with a pre-operative kinematic biomechanical simulator 14 that simulates movement of the joint using the geometric models for use in determining implant positions, including angular orientations, for the components. The implant positions are used in conjunction with the geometric models in intra-operative navigational software 16 to guide a medical practitioner in the placement of the implant components at the implant positions.

The pre-operative geometric planner 12, the pre-operative kinematic biomechanical simulator 14 and the intra-operative navigational software are implemented using a computer system 20 having at least one display monitor 22, as shown in FIG. 3....(DiGioia, Fig. 1; col. 5, l. 63-col. 6, l. 8).

To begin the procedure, a tomographic (three-dimensional) model of the implant target site is created:

The apparatus 10 of FIG. 1 is operated in accordance with the method illustrated in FIG. 2. The skeletal structure of the joint is determined at step 40 using tomographic data (three dimensional) or computed tomographic data (pseudo three dimensional data produced

from a series of two dimensional scans) or other techniques from the skeletal data source 13. Commonly used tomographic techniques include computed tomography (CT), magnetic resonance imaging (MRI), positron emission tomographic (PET), or ultrasound scanning of the joint and surround structure. The tomographic data from the scanned structure generated by the skeletal data source 13 is provided to the geometric planner 12 for use in producing a model of the skeletal structure..... (DiGioia, col. 6, l. 49-61).

A surface model of the target site, and a model of the component to be implanted, are then created:

At step 42, a surface model is created, or constructed, from the skeletal geometric data.... (DiGioia, col. 7, l. 1-3).

Also at step 42, geometric models of the artificial components to be implanted into the joint are created/generated.....(DiGioia, col. 7, l. 11-12).

The software then simulates motion of the target site with the implanted prosthesis to determine the achievable range of motions:

In step 46, the simulated movement of the joint at various implant positions is used to calculate a range of motion for each implant position. In step 48, the calculated ranges of motion are compared to the predetermined range of motion to select an implant position for the artificial components. A goal of the simulation process is to find the implant position which optimizes the calculated range of motion using the predetermined range of motion as a basis for optimization.....(DiGioia, col. 7, l. 46-53).

The model is then aligned with the patient's body using a three-dimensional registration process:

In step 54, the joint model based on the skeletal data is aligned with the intra-operative position of the patient's joint. In a preferred embodiment, step 54 is performed using a technique known as three dimensional (3D) surface registrations. In 3D surface registration, discrete registration points are obtained from the joint skeletal structure to define the intra-operative position of the patient's joint. The registration points are fitted to the joint model of the skeletal structure to determine a coordinate transformation that is used to align the joint model with the intra-operative position of the patient's joint. Once the transformation is established, the intra-operative position of the patient's joint can be tracked using the joint model by obtaining positional data from a point on the joint that provides spatial correspondence between the pre-operative models and the intra-operative measurements.....(DiGioia, col. 8, l. 13-28).

The registration is performed by tracking the position of a sensing device 300 that measures the position of landmarks on the patient's body:

As illustrated in FIG. 3A, the coordinates of the points on the bony surface can be found using a sensing device 300 such as, for example, a pointing probe, an ultrasound probe, *a fluoroscopic imaging device*, an optical range sensor, or a mechanical arm. The sensing device 300 is used to measure the positions of discrete points on the bony surface relative to the sensing device 300. *The position of the sensing device 300 is tracked using the tracking device 30.* Thus, the position of the discrete points on the bony surface can be expressed relative to the tracking device 30, and then registered with the pre-operative plan. The position of a surgical tool 302 can also be tracked intra-operatively by the tracking device 30." (DiGioia, col. 8, l. 59-col. 9, l. , emphasis added; Fig. 3a).

Unlike DiGioia, applicant does not track the position of a sensing device to define the landmarks on a patient. Nor does applicant register the three-dimensional dataset of a target site with actual landmarks on a patient. The disadvantages of a registration approach such as taught by DiGioia and others are explicitly described by applicant at p. 3, l. 5-30 of the present application:

In order to make the requisite measurements, suitable coordinate systems must be established for the pelvis and for the femur. Common landmarks for a pelvic coordinate system are the two anterior superior iliac spines and the pubic symphysis. A variety of techniques are currently used to determine (i.e., measure) these landmarks, including direct digitization with a navigated probe (i.e., a probe having reference elements associated with it whose position in three-dimensional space can accurately be determined); by using preoperative three-dimensional CT or MR scan images of the landmarks and thereafter registering the images with the actual landmarks during the operation; or by making multiple fluoroscopic images of the pelvis intraoperatively, digitizing the selected landmarks on the images, and backprojecting them to determine their actual location. All of these methods are inefficient.

Directly digitizing certain landmarks such as the superior spines or the pubic symphysis by touching the skin or probing through the skin requires that these landmarks be accessible during the surgery. Further, the anterior superior iliac spines are ill-defined, rounded landmarks that are difficult to determine accurately by direct digitization. Similarly, developing a pelvic coordinate system by preoperative three-dimensional imaging has a number of shortcomings. To begin with, the patient must undergo a test preoperatively that might otherwise be unnecessary.

Further, during surgery, the three-dimensional dataset of the pelvis must be "registered" to the actual pelvis, a procedure which itself can be time consuming. Likewise, developing a pelvic coordinate system by obtaining multiple fluoroscopic images and backprojecting is both time consuming and difficult. Frequently the quality of the images is poor, since they must often be taken at angles that require penetration not only of the patient's body but also of the apparatus that stabilizes the patient and of the operating table as well. Finally, attempting to combine directly digitized information with fluoroscopic images is subject to the drawbacks of both methods.

Note that DiGioia does not suggest that the fluoroscopic imaging device itself is capable of determining the orientation of the selected body points: like the other sensing devices mentioned (pointing probe, ultrasound probe, optical range sensor, mechanical arm), its position is tracked by a tracking device and then registered with the preoperative plan.

From the above it can be seen that DiGioia neither teaches nor suggests *any* of the following limitations expressly set forth in claim 4:

- *A method....for determining axial rotation of a pelvis from a single fluoroscopic image,*
- *receiving a fluoroscopic image of said pelvis in the near AP direction;*
- *defining first and second landmarks of said pelvis on said image;*
- *determining the transaxial displacement of said landmarks on said image;*
- *using said displacement to determine the axial rotation of said pelvis with respect to the plane of said fluoroscopic image.*

Similarly, DiGioia neither teaches nor suggests *any* of the following limitations expressly set forth in claim 9:

- *A method....for determining the transaxial rotation of a pelvis from a single fluoroscopic image,*
- *receiving a fluoroscopic image of said pelvis in the near AP direction;*
- *defining first and second landmarks of said pelvis on said image;*
- *determining the axial displacement of said landmarks on said image;*
- *using said displacement as a measure of the transaxial rotation of said pelvis*



*with respect to the plane of said fluoroscopic image.*

DiGioia is wholly insufficient, either alone or in combination with Sarin, to teach or suggest applicant's invention.

With respect to the Examiner's comments that Sarin teaches "the second landmark to comprise the midpoint of a line between the image points on the left and right sacroiliac joints", applicant does not claim that the use of these points as landmarks is novel outside the context of the claimed invention. See applicant's disclosure quoted at p. 12 above. However, in the context of the invention as claimed in claims 4 and 9, it clearly is novel. Nothing in either Sarin or DiGioia suggest extracting rotational information from the recited landmarks.

## II.

Claims 7-8 and 12-13 have been rejected under 35 U.S.C. 103(a) as being unpatentable over Sarin modified by DiGioia as applied to claims 1 and 9 above, and further in view of Chen et al. (WO 02/062248).

Chen is another example of the use of digitizing or "localizing" systems to define a surgical coordinate system:

According to the invention, there is provided a method of defining a three dimensional coordinate system using three landmarks associated with an anatomical structure that are digitized using a digitization device, and imaging to refine a location for these landmarks. (Chen, p. 3, l. 21-24).

The resultant digitized landmarks may be "refined" through the use of "at least one" X-ray image:

A further aspect of the invention includes the identification of three pelvic landmarks used to define the frontal and sagittal plane of a pelvis. These planes are used to define a three-dimensional coordinate system for use in a computer assisted surgical system. The pelvic locations of landmarks are identified using a digitization device and refined using at least one calibrated X-ray image. (Chen, p. 4, l. 21-25).

A fluoroscopic imaging system is one of several that are suggested for use since such systems are commonly available in operating rooms:

Referring to Figure 1, a computer-assisted acetabular cup positioning apparatus includes a mobile fluoroscopic C-arm X-ray imaging device 20. Mobile X-ray devices used in the operating room are generally known as C-arms due to their shape. The imaging method is referred to as 'fluoroscopy' since no X-ray film is being used. Fluoroscopy-based navigation systems are commercially available and very common in operating rooms.

While the embodiment of the invention described is in reference to fluoroscopic-based navigation, it can be appreciated that other imaging modalities may be used, for example, computerized tomography (CT), magnetic resonance imaging (MR!), ultrasound, and bi-planar X-ray. However, for certain of these modalities, there is an additional need for pre-operative tomographic imaging, fiducial placement or intra-operative matching of tomographic datasets. (Chen, p. 6, l. 11-23).

X-Rays of the patient are taken at multiple orientations:

By orbitally and laterally rotating the C-arm 22 about the free space 34, X-rays may be directed to pass through the patient 52 along multiple planes to generate two-dimensional images from different perspectives. . (Chen, p. 7, l. 6-8).

Images of radio-opaque beads are taken to enable calculation of the distortion of the X-ray system:

The computer system 40 is further provided with software such as SNN Fluoro™ software, and the like, that allows for the acquisition and registration of fluoroscopic images and superimposition of optically-tracked instruments.

The image receptor assembly 32 is further fitted with two calibration plates 46, which are clamped onto the image intensifier 36. The calibration plates 46 contains radio-opaque beads spaced in a well-defined geometry and are positioned adjacent to the image intensifier 36 in the path of incoming X-ray photons emitted from the X-ray source 30. The raw, unprocessed images as captured by the image intensifier 36 are overlaid with the images of the radio opaque beads. The images of the beads will appear distorted from their true geometry following X-ray transmission through the calibration plate 46.

Information regarding the actual positioning of the radio-opaque beads previously stored in the computer 42 is used in a mathematical model to compute image distortion. (Chen, p. 7, l. 6-8).

A patient tracker is then firmly affixed to the patient at designated landmarks:

The patient tracker 48 is an active or passive optically-tracked instrument. The patient tracker 48 is rigidly attached to the patient in close proximity to the interested area. In THR, the patient tracker 48 is attached to the frontal iliac crests of the pelvis 60 and 62, as indicated in Figure 2, for example, using Kirschner wires which are drilled by the surgeon into the iliac crests 60 and 62. For accurate image guidance, the patient tracker 48 cannot be significantly moveable relative to the patient 52 and is preferably substantially immovable; although, a less rigidly secured tracker may be acceptable in certain applications, for example, visualization and simulation. It will be appreciated that any movement of the patient tracker relative to the patient will affect the accuracy of any subsequent computation based on the location of the patient tracker 48.

The patient tracker 48 is used in conjunction with a position sensing system, as further described below. (Chen, p. 9, l. 17-29).

The patient tracker registers the position of instruments to the fluoroscopic images:

The function of the patient tracker 48 is to determine the transformation between image coordinate and world coordinate systems (i.e. the actual coordinates of objects in the operating room). These transformations are necessary to render optically-tracked instruments (such as drill guides, probes, awls, etc.) on the fluoroscopic image in the correct anatomical position. (Chen, p. 11, l. 1-5).

It is the tracker that determines the position and orientation of an object:

A tracker is a device that tracks the position and orientation of a rigid body. A tracker can include several components, for example, optical or acoustical markers that are used to determine a rigid object's position and orientation in space. (Chen, p. 11, l. 19-22).

The location in three-dimensional space of selected landmarks is then determined using the tracked probes:

Once the patient 52 within the free space 34 is fitted with the patient tracker 48, reference points, or landmarks, are identified to define the frontal plane of the patient. The landmarks may be anatomically significant structures, points, virtual points, prominences, and the like, suitable for plane definition and fast identification by the user. With reference to the human pelvis 64, the frontal plane of a person standing in upright position is defined by three landmarks on the pelvis (Figure 2): left anterior superior iliac spine 66, right anterior superior iliac spine 68 and the centre of the pubis symphysis 70. As will be appreciated by persons skilled in the art, other landmarks may be ascertained and used to define the frontal or other planes for other anatomical structures, including other ball and socket joints on human, mammalian or other vertebrates.

For an accurate definition of the frontal plane of the human pelvis, it is preferred that both anterior superior iliac spine landmarks 66 and 68 are on the same height level in the anterior posterior and in the sagittal planes, and that the landmark on the pubic symphysis 66 is centered in the anterior posterior plane, as depicted in Figure 2.

The three landmarks can be substantially identified by palpation by the surgeon, or other practitioner familiar with anatomy, using known techniques. The user then uses digitization devices such as a tracked probe 96 to determine the three-dimensional coordinate position of the three landmarks 66, 68 and 70. Preferably, the tracked probe 96 is a needle pointer capable of piercing the skin to contact the underlying bone. The needle pointer 96 has a tracking component 98 attached to the handle 100 of the probe. The location and orientation of the trajectory of the tip 102 of the needle relative to the tracking element 98 is known and communicated to the navigation software. (Chen, p. 12, l. 11-p. 12, l. 5).

Finally, the digitized positions are registered to an X-ray image of the selected landmarks so that the digitized measurements can be corrected to more accurately overlie the desired landmarks:

Using imaging techniques, the digitized positions of landmarks are refined in order to compensate for any inaccuracies in the user's location of the landmarks. For example, a single anterior-posterior X-ray view of the interested anatomical area is taken and the digitized position of a landmark within the plane normal to the X-ray beam direction can be adjusted in imaging software, or the like, accordingly. More particularly, the digitized position of the landmarks as displayed on the computer display 44 may be adjusted (i.e. left, right, up or down) relative to the planar X-ray image, without modifying the depth of the point so as to coincide therewith. For example, the rough positions of the left anterior

superior iliac spine 66, right anterior superior iliac spine 68, and the centre of pubis symphysis 70, obtained with the digitizing instrument, are adjustable to overlay the X-ray image of the landmarks. Alternatively, lateral or other X-ray views may also be used for fine adjustment depending on the procedure to the patient. In the further alternative, ultrasound imaging may be used for refining landmark coordinates. (Chen, p. 13, l. 6-20).

As should be unambiguously clear from the above, Chen uses the landmark images solely to ensure that the digitizing probe is indeed located over the desired landmark. Chen does **not** use the landmark images to measure rotation of the plane defined by these landmarks. Nor does Chen teach finding the distance from the pubic symphysis to the right and left teardrops. The Chen disclosure is totally silent as to this. As was the case with Sarin and DiGioia, Chen neither teaches nor suggests **any** of the following limitations expressly set forth in claim 4:

●*A method....for determining axial rotation of a pelvis from a single fluoroscopic image,*  
●*receiving a fluoroscopic image of said pelvis in the near AP direction;*  
●*defining first and second landmarks of said pelvis on said image;*  
●*determining the transaxial displacement of said landmarks on said image;*  
●*using said displacement to determine the axial rotation of said pelvis with respect to the plane of said fluoroscopic image.*

nor **any** of the following limitations expressly set forth in claim 9:

●*A method....for determining the transaxial rotation of a pelvis from a single fluoroscopic image,*  
●*receiving a fluoroscopic image of said pelvis in the near AP direction;*  
●*defining first and second landmarks of said pelvis on said image;*  
●*determining the axial displacement of said landmarks on said image;*  
●*using said displacement as a measure of the transaxial rotation of said pelvis with respect to the plane of said fluoroscopic image.*

There is no basis in Chen for forming a combination with either Sarin or DiGioia, nor can such a combination supply a teaching that is clearly absent in each of them.

Applicant's claims are clearly patentable over each of these references, singly or in any combination.

**III.**

The Examiner's "Response To Arguments" admits that Sarin does not teach taking an image but asserts that Sarin does teach manipulating landmarks on an image. How does one manipulate landmarks on a non-existent image? The fact is, as shown above, Sarin simply does not do so.

DiGioia's "mapping of landmarks" is explained fully above. The images of the landmarks are used simply to locate the digitizers, not for themselves providing measurements.

In brief, the Examiner is simply using applicant's teaching to reconstruct Sarin, DiGioia and Chen to do what they never contemplated doing.

We again request that the Examiner reconsider the requirement for restriction as to claims 15-21. As set forth in our Response of May 12, 2009 which contained a detailed comparison of the elements of claims 15 with those of claims 4 and 9, claim 15 is clearly for the same invention as those of claims 4 and 9. Requiring a separate application for presentation of claim 15 and its dependent claims is simply wasteful, and benefits neither the patent and Trademark Office nor the public. Reconsideration is respectfully requested.

Please charge any additional fee occasioned by this paper to our Deposit Account No. 03-1237.

Respectfully submitted,

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